Second Regular Session 112th General Assembly (2002)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2001 General Assembly.

HOUSE ENROLLED ACT No. 1233

AN ACT to amend the Indiana Code concerning human services.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 12-7-2-51.8 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: **Sec. 51.8. "Cross-indicated drug", for purposes of IC 12-15-35.5, has the meaning set forth in IC 12-15-35.5-2.**

SECTION 2. IC 12-7-2-178.5 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 178.5. "Single source drug" ~~for purposes of IC 12-15-35-35, has the meaning set forth in IC 12-15-35-35(a).~~ **means an outpatient drug that is produced or distributed under an original new drug application approved by the federal Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.**

SECTION 3. IC 12-15-35-35, AS AMENDED BY P.L.231-1999, SECTION 6, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 35. ~~(a) As used in this section, "single source drug" means a covered outpatient drug that is produced or distributed under an original new drug application approved by the federal Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.~~

~~(b)~~ **(a)** Before the board develops a program to place a single source drug on prior approval, restrict the drug in its use, or establish a drug

monitoring process or program to measure or restrict utilization of single source drugs other than in the SURS program, the board must meet the following conditions:

(1) Make a determination, after considering evidence and credible information provided to the board by the office and the public, that placing a single source drug on prior approval or restricting the drug's use will not:

(A) impede the quality of patient care in the Medicaid program; or

(B) increase costs in other parts of the Medicaid program, including hospital costs and physician costs.

(2) Meet to review a formulary or a restriction on a single source drug after the office provides at least thirty (30) days notification to the public that the board will review the formulary or restriction on a single source drug at a particular board meeting. The notification shall contain the following information:

(A) A statement of the date, time, and place at which the board meeting will be convened.

(B) A general description of the subject matter of the board meeting.

(C) An explanation of how a copy of the formulary to be discussed at the meeting may be obtained.

The board shall meet to review the formulary or the restriction on a single source drug at least thirty (30) days but not more than sixty (60) days after the notification.

(3) Ensure that:

(A) there is access to at least two (2) alternative drugs within each therapeutic classification, if available, on the formulary; and

(B) a process is in place through which a Medicaid recipient has access to medically necessary drugs.

(4) Reconsider the drug's removal from its restricted status or from prior approval not later than six (6) months after the single source drug is placed on prior approval or restricted in its use.

(5) Ensure that the program provides either telephone or FAX approval or denial Monday through Friday, twenty-four (24) hours a day. The office must provide the approval or denial within twenty-four (24) hours after receipt of a prior approval request. The program must provide for the dispensing of at least a seventy-two (72) hour supply of the drug in an emergency situation or on weekends.

(6) Ensure that any prior approval program or restriction on the

use of a single source drug is not applied to prevent acceptable medical use for appropriate off-label indications.

~~(c)~~ **(b)** The board shall advise the office on the implementation of any program to restrict the use of brand name multisource drugs.

~~(d)~~ **(c)** The board shall consider:

(1) health economic data;

(2) cost data; and

(3) the use of formularies in the non-Medicaid markets;

in developing its recommendations to the office.

SECTION 4. IC 12-15-35.5 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]:

Chapter 35.5. Prescription Drugs

Sec. 1. (a) Except as provided in subsection (b), this chapter applies to:

(1) the Medicaid program under this article; and

(2) the children's health insurance program under IC 12-17.6.

(b) This chapter does not apply to a formulary or prior authorization program operated by a managed care organization under a program described in subsection (a).

Sec. 2. As used in this chapter, "cross-indicated drug" means a drug that is used for a purpose generally held to be reasonable, appropriate, and within the community standards of practice even though the use is not included in the federal Food and Drug Administration's approved labeled indications for the drug.

Sec. 3. (a) Except as provided in subsection (b), the office may establish prior authorization requirements for drugs covered under a program described in section 1(a) of this chapter.

(b) The office may not require prior authorization for the following single source or brand name multisource drugs:

(1) A drug that is classified as an antianxiety, antidepressant, or antipsychotic central nervous system drug in the most recent publication of Drug Facts and Comparisons (published by the Facts and Comparisons Division of J.B. Lippincott Company).

(2) A drug that, according to:

(A) the American Psychiatric Press Textbook of Psychopharmacy;

(B) Current Clinical Strategies for Psychiatry;

(C) Drug Facts and Comparisons; or

(D) a publication with a focus and content similar to the publications described in clauses (A) through (C);

is a cross-indicated drug for a central nervous system drug classification described in subdivision (1).

(3) A drug that is:

(A) classified in a central nervous system drug category or classification (according to Drug Facts and Comparisons) that is created after the effective date of this chapter; and

(B) prescribed for the treatment of a mental illness (as defined in the most recent publication of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders).

(c) Except as provided under section 7 of this chapter, a recipient enrolled in a program described in section 1(a) of this chapter shall have unrestricted access to a drug described in subsection (b).

Sec. 4. Prior authorization requirements developed under this chapter must:

(1) comply with all applicable state and federal laws, including the provisions of 405 IAC 5-3 and 42 U.S.C. 1396r-8(d)(5); and

(2) provide that the prior authorization number assigned to an approved request be included on the prescription or drug order:

(A) issued by the prescribing physician; or

(B) if the prescription is transmitted orally, relayed to the dispensing pharmacist by the prescribing physician.

Sec. 5. Before requiring prior authorization for a single source drug, the office shall seek the advice of the drug utilization review board, established by IC 12-15-35-19, at a public meeting of the board.

Sec. 6. (a) The office shall publish the decision to require prior authorization for a single source drug in a provider bulletin.

(b) IC 12-15-13-6 applies to a provider bulletin described in subsection (a).

Sec. 7. (a) Subject to subsection (b), the office may place limits on quantities dispensed or the frequency of refills for any covered drug for the purpose of:

(1) preventing fraud, abuse, waste, overutilization, or inappropriate utilization; or

(2) implementing a disease management program.

(b) Before implementing a limit described in subsection (a), the office shall:

(1) consider quality of care and the best interests of Medicaid

recipients;

(2) seek the advice of the drug utilization review board, established by IC 12-15-35-19, at a public meeting of the board; and

(3) publish a provider bulletin that complies with the requirements of IC 12-15-13-6.

SECTION 5. IC 12-17.6-4-2.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: **Sec. 2.5. Prescription drugs provided under the program are subject to the requirements of IC 12-15-35.5.**

SECTION 6. IC 12-15-32-11, AS AMENDED BY P.L.291-2001, SECTION 216, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 11. (a) The office may assess community residential facilities for the developmentally disabled (as defined in IC 12-7-2-61) and intermediate care facilities for the mentally retarded **(ICF/MR)** (as defined in IC 16-29-4-2) that are not operated by the state in an amount not to exceed ten percent (10%) of the **total** annual ~~gross residential services~~ revenue of the facility for the facility's preceding fiscal year.

(b) The assessments shall be paid to the office of Medicaid policy and planning in equal monthly amounts on or before the tenth day of each calendar month. The office may withhold Medicaid payments to a provider described in subsection (a) that fails to pay an assessment within thirty (30) days after the due date. The amount withheld may not exceed the amount of the assessments due.

(c) Revenue from the assessments shall be credited to a special account within the state general fund to be called the Medicaid assessment account. Money in the account may be used only for services for which federal financial participation under Medicaid is available to match state funds. An amount equivalent to the federal financial participation estimated to be received for services financed from assessments under subsection (a) shall be used to finance Medicaid services provided by facilities described in subsection (a).

(d) If federal financial participation to match the assessments in subsection (a) becomes unavailable under federal law, the authority to impose the assessments terminates on the date that the federal statutory, regulatory, or interpretive change takes effect.

SECTION 7. **An emergency is declared for this act.**

Speaker of the House of Representatives

President of the Senate

President Pro Tempore

Approved: _____

Governor of the State of Indiana